MINIATURE, PULSATILE IMPLANTABLE VENTRICULAR ASSIST DEVICES AND METHODS OF CONTROLLING VENTRICULAR ASSIST DEVICES

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Application No. 60/431,288, filed December 6, 2002, which is incorporated by reference herein.

FIELD OF THE INVENTION

[0002] The present invention relates to devices and associated methods for pumping fluids, for example, blood. More particularly, the present invention relates to implantable ventricular assist devices (VADs) that are utilized to replace the function of either the right ventricle or the left ventricle, or both, of the heart. The ventricular assist devices of the present invention include certain features that relate in the art to electric pulsatile devices.

BACKGROUND OF THE INVENTION

[0003] Four hundred thousand new cases of congestive heart failure are diagnosed in the United States annually, a number which will only rise in the foreseeable future with the aging of the baby-boom generation. According to the Framingham Heart Study, the five-year mortality rate for patients with congestive heart failure was 75 percent in men and 62 percent in women. Standard medical and surgical therapies benefit only a small percentage of patients with ventricular dysfunction. Potential cardiac transplant recipients with hemodynamic instability may receive temporary mechanical circulatory support, such as an implantable blood pump, as a bridge to cardiac transplantation. Moreover, estimates in the field suggest that 17,000 to 66,000 patients each year in the United States may benefit from a permanent implantable blood pump.

[0004] The ventricular assist device (VAD) is a blood pump designed to assist or replace the function of either ventricle, or both ventricles, of the heart. A right ventricular assist device (RVAD) supports pulmonary circulation by receiving or withdrawing blood from the right ventricle and returning it to the pulmonary artery. A left ventricular assist device (LVAD) supports systemic perfusion by receiving or withdrawing blood from the left ventricle (or left atrium) and returning it to the aorta. A biventricular assist device (BVAD) supports both ventricles of the heart. Ventricular assist devices may be either implantable or extracorporeal,

with implantable VADs positioned intracorporeally in the anterior abdominal wall or within a body cavity (other than the pericardium) and with extracorporeal VADs located paracorporeally, along the patient's anterior abdominal wall, or externally at the patient's bedside.

[0005] The first ventricular assist devices attempted to mimic the pulsatile flow of the natural left ventricle by utilizing flexible chambers with volumes approximately equal to the volume of the respective ventricle being assisted. The typical volume of blood expelled by the left ventricle of an adult is between 70-90 ml, but may range from 40-120 ml. The chambers are expanded and contracted, much like a natural ventricle, to alternately receive and expel blood. One way valves at the inlet and outlet ports of the chambers ensured one way flow therethrough.

[0006] So-called "pulsatile pumps" may include one or a pair of driven plates for alternately squeezing and expanding flexible chambers. The flexible chambers typically comprise biocompatible segmented polyurethane bags or sacs. The blood sac and drive mechanism are mounted inside a compact housing that is typically implanted in the patient's abdomen. A controller, backup battery, and main battery pack are electrically connected to the drive mechanism. Even the most basic drive mechanisms of the prior art are relatively complex and expensive, and typically incorporate some type of mechanical cam, linkage, or bearing arrangement subject to wear.

[0007] Because of the varying volume of the blood sac within the rigid encapsulation housing of pulsatile pumps, accommodation must be made for the air displaced thereby. Some devices utilize a percutaneous tube vented to the atmosphere, which is a simple approach but has the disadvantage of a skin penetration and associated infection risk. Another approach, proposed for fully-implantable VAD systems, is to use a volume compensator. This is a flexible chamber, implanted in the thoracic cavity adjacent to the lungs and communicating with the air space within the housing and outside the blood sac via an interconnecting tube. As the blood sac expands with incoming blood, air is displaced from the housing to the volume compensator. Conversely, expulsion of blood from the blood sac creates a negative pressure within the housing and pulls air from the volume compensator. While eliminating the infection risk of the percutaneous vent, the volume compensator poses certain challenges: increased system complexity, an additional implanted component and potential site of infection, maintaining long-

term compliance of the implanted volume compensator sac, problems associated with gas diffusion in or out of the enclosed volume, and problems associated with changes in ambient pressure, such as experienced during a plane flight.

[0008] One example of an electric pulsatile blood pump is the Novacor N100 Left Ventricular Assist System (World Heart Inc., Oakland, Calif.). This system contains a single polyurethane blood sac with a nominal stroke volume of 70 ml that is compressed by dual symmetrically opposed pusher plates in synchronization with the natural left ventricle contraction. The pusher plates are actuated by a spring-decoupled solenoid energy converter. The blood pump and energy converter are contained within a housing that is implanted in the patient's abdomen. The N100 employs a percutaneous vent tube that also carries power and control wires.

[0009] An example of an electric pulsatile blood pump not requiring external venting is disclosed in U.S. Patent No. 6,264,601 ("the '601 patent"), incorporated herein by reference. The system of the '601 patent has two pumping chambers formed from two flexible sacs separated by a pusher plate, with the sacs and pusher plate contained within one housing. An electromagnetic drive system acts on an iron armature surrounded by a cylindrically symmetric permanent magnet within the pusher plate to alternatively pump blood through the two sacs by compressing one sac and then the other against the housing. Since each sac contains only fluid that is alternately received and discharged as the pusher plate reciprocates, the total volume of the pump remains constant during pumping and no venting or volume compensator is required. The input and output of each sac includes a one-way valve, providing unidirectional flow that pumps the fluid in a preferred direction. The most efficient use of the electromagnetic drive system is achieved when the power and energy required in each pump stroke is approximately equal.

[0010] The '601 patent describes several alternative arrangements for using a blood pump, including a left or right VAD that couples the input and output flows from each chamber in either parallel or series, and a BVAD that separately uses two separate VADs to assist the left and right ventricle. One embodiment described in the '601 patent is a series-displacement pump, in which a first chamber receives a fluid for pumping, and provides that fluid to the input of a second chamber for further pumping ("the '601 series-displacement pump"). In operation, the '601

series displacement pump alternates between a pump stroke and a transfer stroke. When used as a VAD, the pump stroke pumps blood from the second chamber into the aorta while blood is drawn from the ventricle into the first chamber. In the transfer stroke, blood from first chamber is transferred to the second chamber. The fluid connection between the chambers is an external transfer conduit that connects the output of the first sac to the input of the second sac.

[0011] The '601 series-displacement pump has several advantages over other prior art pumps including, but not limited to, the ability to provide pulsatile flow, the use of fewer blood conduits and valves, and reduced size. However, the electromagnetic drive system of the '601 patent is optimized for bi-directional use, while the power and transfer strokes of the '601 series-displacement pump each have different power and energy characteristics. While the pump of the '601 patent is capable of operating as a series-displacement pump, there are energy losses that result from not having the drive and pump matched for series operation. Also, in general, the pump of the '601 patent includes a permanent magnet to drive the pusher plates that has a radially symmetric design that is expensive and difficult to manufacture.

[0012] Series-displacement pumps generally provide fluid communication between chambers through external conduits. Examples of series-displacement pumps using external conduits include the '601 series-displacement pump, and the pump-driven diaphragm pump and a pusher plate driven pump between two variable-volume chambers as described in U.S. Pat. Nos. 4,468,177 and 4,547,911 to Strimling. The Strimling devices are similar to the '601 pump in that each of the Strimling devices may function either as a BVAD heart pump with each chamber communicating separately with a respective ventricle of the heart, or as a single ventricle-assist pump wherein the two chambers are connected in series with a shunt therebetween.

[0013] In recent years there has been increased study into the potential of using rotary pumps (centrifugal or axial) for ventricular assist. These pumps employ fast-moving impellers to impart forward flow to the blood. The impellers are either supported by bearings or are magnetically levitated. A significant advantage of rotary pumps is their relatively compact size and low cost. In addition, the pressure difference maintained by the impeller eliminates the need for one-way valves as in pulsatile pumps. Finally, no venting or volume compensator is necessary.

[0014] The use of rotary pumps has generated a significant amount of interest in this field, but as yet many drawbacks prevent general acceptance. For instance, bearing-supported impellers usually require lubrication that must be absolutely kept out of contact with the blood, thus requiring seals that remain highly effective for extended periods. In some designs, the bearings are within the pump housing in contact with blood, which is then used as the lubricating fluid and may be subject to degradation. In addition, the heat generated by some bearing configurations may adversely affect the blood. Some designs eschew bearings altogether and instead utilize magnetically levitated impellers. However, these are relatively complex and sometimes unstable.

[0015] A safety issue with rotary pumps is their non-occlusive character, which provides a shunt path for blood regurgitation if the impeller is not rotating. That is, the one-way valves in pulsatile pumps ensure a uni-directional pathway through which blood is propelled, and prevent regurgitation from the arterial vessel if the device shuts off or fails. The natural ventricle can thus function as a back-up perfusion system, bypassing the pump circuit. If the impeller in a rotary pump stops, however, a flow path is created permitting blood from the arterial vessel to be shunted through the pump back into the ventricle, thus seriously impairing the back-up capability of the natural ventricle. To prevent this situation, a one-way valve or occluder of some sort must be provided at the rotary pump outflow. A still further issue with rotary pumps, as yet to be resolved, is the efficacy of the continuous flow of blood provided thereby. There is considerably less experience in the use of long-term circulatory support with continuous flow pumps as opposed to a vast body of experience with pulsatile flow pumps.

[0016] In view of the foregoing, there is an ongoing need in the art to improve upon conventional ventricular assist devices, and in particular upon series-displacement pumps. For example, reductions in size and the reduction of weight of the drive units would be advantageous to facilitate full implantation of a device. In addition, it would be advantageous to more closely match the power and operating speeds of pulsatile, series-displacement pumps to provide efficiently use of power over the cardiac cycle while providing pumping during systole. Further, a device that is low in cost but does not have the disadvantages of rotary pumps would be advantageous for long-term use. Accordingly, there remains a need in the art for a small,

efficient, atraumatic, and fully implantable series-displacement ventricular assist device that overcomes the deficiencies of conventional devices.

[0017] Therefore, it is one aspect of the present invention to provide a ventricular assist device that is smaller, more robust and more efficient than prior art ventricular assist devices.

[0018] It is another aspect of the present invention to provide a ventricular assist device driven by an electromagnetic device at physiological speeds with high pump efficiency.

[0019] It is one aspect of the present invention to provide an electromagnetic drive useful for a ventricular assist device that has constant force characteristics, and that produces a pressure under rest conditions.

[0020] It is yet another aspect of the present invention to provide an electromagnetic drive useful for a ventricular assist device that produces a force that varies approximately linear with the coil current of the drive.

[0021] It is yet another aspect of the present invention to provide an electromagnetic drive useful for a ventricular assist device that can be easily controlled to produce desired output pressures.

[0022] It is another aspect of the present invention to provide a ventricular assist device that nominally beats once per heart beat using an electromagnetic drive that is optimized for efficiency and weight.

SUMMARY OF THE INVENTION

[0023] The present invention provides a pumping system for assisting one or both ventricles of the heart. The pumping system of the invention has a relatively small size and is free of many disadvantages inherent in conventional blood pumps. In addition, the pumping system of the present invention can provide pulsatile flow during systole. Accordingly, the present invention provides a pumping system that is small, efficient, atraumatic, and fully implantable while overcoming the deficiencies of conventional devices.

[0024] In accordance with one aspect of the present invention, a ventricular assist device is provided having a blood pump with an electromagnetic drive that uses springs to produce a constant force biased towards the high pressure side of the pump.

[0025] In accordance with another aspect of the present invention, a ventricular assist device is provided that has a pair of variable-volume chambers situated on either side of an actuator plate having an internal transfer valve therethrough.

[0026] In accordance with yet another aspect of the present invention, a ventricular assist device is provided that pumps nominally once per cardiac cycle and that dynamically ejects blood at the end of a power stroke, thus reducing the required size of the pumping chambers.

[0027] In accordance with one aspect of the present invention, a ventricular assist device is provided having an actuator plate between a pair of serially connected pumping chambers that includes a spring bias for pre-pressurizing a pumping chamber.

[0028] In accordance with yet another aspect of the present invention, a ventricular assist device is provided that can be used for either right or left ventricular assist.

[0029] In accordance with yet another aspect of the present invention, a ventricular assist device is provided that can be used for right and left ventricular assist. In one embodiment, separate devices are provided for each ventricle. In another embodiment, a ventricular assist device is provided that can be used for both right and left ventricular assist with one device.

[0030] In accordance with one aspect of an embodiment of the present invention, a bias force and energy storage device are provided to allow the drive unit to be used at a nearly constant power level while providing a higher output pressure to the systemic circulation.

[0031] In accordance with another aspect of the present invention, a ventricular assist device is provided having an actuator plate (also referred to herein as a "pusher plate") between a pair of serially connected pumping chambers that operate in a two-stroke mode, specifically a power stroke and a transfer stroke, and which includes a spring bias for storing energy from a drive unit during the transfer stroke to augment the pressure generated during the power stroke.

[0032] In accordance with yet another aspect of the present invention, a ventricular assist device is provided having an actuator plate between a pair of serially connected pumping chambers that includes a spring for suspending the actuator plate between the chambers and stabilizing the plate from tilting forces.

[0033] In accordance with one aspect of the present invention, a ventricular assist device is provided that triggers pumping based on contracting of the ventricle. In one embodiment, triggering is based on sensing of the ventricular pressure. In another embodiment, triggering is based on the motion of an element internal to the pump.

[0034] In accordance with yet another aspect of the present invention, a ventricular assist device is provided having an electromagnetic drive that provides adjustment to the pump pressure according to the current through an electromagnet. In one embodiment, the force is biased towards a high pressure portion of the pump.

[0035] In accordance with yet another aspect of the present invention, a ventricular assist device is provided having an electromagnetic drive that provides adjustment to the pump pressure according to the current through an electromagnet. In one embodiment, the force is proportional to the coil current and is approximately independent of the position of a pump actuator.

[0036] In accordance with one aspect of the present invention, a ventricular assist device is provided having an electromagnetic drive with multiple sensors for controlling pump operation.

[0037] In accordance with yet another aspect of the present invention, a method for controlling a ventricular assist device provides for initiation of the device as a function of changes in ventricular pressure.

[0038] In accordance with another aspect of the present invention, a ventricular assist device is provided by a pump having a frame formed from a soft magnetic material and a pair of compressible chambers connected in series and disposed in the frame. The pair of compressible chambers includes a first chamber connected to the device inlet and a second chamber connected to the device outlet. The device also includes an armature and a one-way valve. The armature is disposed between each of the pair of compressible chambers and movable within the frame to simultaneously contract one of the pair of chambers and expand the other of the pair of chambers. The one-way valve provides fluid communication between the pair of chambers in a direction from said first chamber to said second chamber. The motion of the armature towards said first chamber transfers a fluid within the first chamber to the second chamber. The motion of the armature towards the second chamber fills the first chamber from the inlet and empties

said second chamber into the outlet. The device also includes an electromagnetic drive disposed within the frame and adapted to alternately force the armature against one and the other of the pair of compressible chambers. In one embodiment, a second one-way valve is provided at the outlet of the second chamber.

[0039] In accordance with yet another aspect of the present invention, a ventricular assist device is provided by a pump having a frame formed from a soft magnetic material and a pair of compressible chambers connected in series and disposed in the frame. The pair of compressible chambers includes a first chamber connected to the device inlet and a second chamber connected to the device outlet. The device also includes an armature, a one-way valve, and a drive unit. The armature is disposed between each of the pair of compressible chambers and movable within the frame to simultaneously contract one of the pair of chambers and expand the other of the pair of chambers. The one-way valve provides fluid communication between the pair of chambers in a direction from the first chamber to the second chamber, where the motion of the armature towards said first chamber is a transfer stroke that transfers a fluid within the first chamber to the second chamber, and where the motion of the armature towards the second chamber is a power stroke that fills the first chamber from the inlet and empties the second chamber into the outlet. The drive unit includes an electromagnetic drive disposed within the frame and an energy storage element disposed between the frame and the armature. During the transfer stroke, electric power delivered to the electromagnetic drive is stored in the energy storage element, and during the power stroke, electric power delivered to the electromagnetic drive and the stored energy is delivered to the armature. In one embodiment, a second one-way valve is provided at the outlet of the second chamber.

[0040] In accordance with one aspect of the present invention, an electromagnetic drive is provided having one or more magnets arranged about a common axis.

[0041] In accordance with another aspect of the present invention, an electromagnetic drive is provided having springs for counterbalancing the attraction of magnets in an armature to the metal of a frame. In one embodiment, the counterbalancing provides a drive that, in the absence of an applied current, has a bias force that is approximately independent of armature position.

According to another embodiment, the force produced by the drive is proportional to the applied current and approximately independent of the armature position.

[0042] In accordance with yet another aspect of the present invention, a electromagnetic drive is provided by a device having a frame formed from a soft magnetic material; one or more coils disposed within the frame that, when electrically energized, generate a magnetic flux and define one or more pairs of magnetic poles each having a polar axis; an armature within the frame having a magnetic core, a non-magnetic material surrounding the core, and one or more magnets in the non-magnetic material, wherein the core is movable along the polar axis, and where the poles of the one or more magnets are oriented perpendicular to the polar axis with like oriented pole aligned towards the polar axis; and one or more springs positioned between the frame and the armature so as to exert a spring force on the armature; wherein one or more magnets generate a magnet force on the armature resulting from the attraction of the magnet to the frame when the pair of coils is not electrically energized, wherein the sum of the spring forces and the magnetic force is a net bias force that is approximately independent of the position of the armature along the polar axis and biases the armature towards one of the pair of poles, and wherein the energized coils generate a coil force on the armature that is approximately independent of the position of the armature along the polar axis and that varies according to the degree of energization of the coils.

[0043] In accordance with yet another aspect of the present invention, a ventricular assist device is provided by a device including a blood pump connected to a heart and adapted to pump blood from the ventricle to the aorta, a drive system to supply power to the pump, a sensor adapted to detect responses increases in the ventricular pressure; and a controller for actuating the blood pump upon sensing an increase in the ventricular pressure.

[0044] Broadly stated, the present invention provides a ventricular assist device for pumping blood between an inlet and an outlet, the device comprising: a frame; a pair of compressible chambers disposed within the frame, the pair of compressible chambers including a first chamber connected to the inlet and a second chamber connected to the outlet; an actuator disposed between the pair of compressible chambers and movable therebetween, where the movement of the actuator increases the volume of one of the pair of compressible chambers and decreases the

volume of the other of the pair of compressible chambers; and a one-way valve for providing fluid communication from the first chamber to the second chamber; and a drive unit adapted to alternately move the actuator towards one or the other of the pair of compressible chambers, wherein the movement of the actuator towards the first chamber is a transfer stroke that transfers a fluid within the first chamber to the second chamber, and wherein the movement of the actuator towards the second chamber is a pump stroke that fills the first chamber from the inlet and empties the second chamber into the outlet.

[0045] A further understanding of the invention can be had from the detailed discussion of the specific embodiments below. It is therefore intended that the invention not be limited by the discussion of specific embodiments.

[0046] Additional objects, advantages, aspects and features of the present invention will become apparent from the description of embodiments set forth below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0047] The foregoing aspects and the attendant advantages of the present invention will become more readily appreciated by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

[0048] FIG. 1A is a perspective view of a ventricular assist system of the present invention connected to a heart of a patient for left ventricular assist;

[0049] FIG. 1B is top view of the pumping portion of the present invention including a cut-way showing the blood pump;

[0050] FIG. 2 is a perspective view of the first embodiment blood pump of the invention;

[0051] FIG. 3 is a top view of a first embodiment blood pump of the invention;

[0052] FIG. 4 is a sectional view of the first embodiment blood pump of the invention taken along line 4--4 of FIG. 3;

[0053] FIG. 5A is a sectional view of the first embodiment blood pump of the invention taken through the magnets along line 5A—5A of FIG. 3;

[0054] FIG. 5B is a sectional view of the first embodiment blood pump of the invention taken through the internal transfer portion along line 5B—5B of FIG. 3;

[0055] FIG. 6A is a sectional view of the actuator plate of the first embodiment blood pump of the present invention taken along line 6--6 of FIG. 5A;

[0056] FIG. 6B is a sectional view of an alternative embodiment actuator plate having two transfer ports and taken along line 6--6 of FIG. 5A;

[0057] FIGS. 7A to 7F are schematic views of one configuration of pumping chambers of the present invention;

[0058] FIG. 8A is a schematic view of an exemplary drive structure of the invention, illustrating a magnetic flux path generated by a magnet on an armature, shown in an equilibrium position;

[0059] FIG. 8B is a view similar to that of FIG. 8A, showing the armature displaced to the right and being driven to the left and illustrating the magnetic flux paths including a coil flux path generated by a fixed electromagnetic coil;

[0060] FIG. 8C is a view similar to that of FIG. 8A, showing the armature displaced to the left and being driven to the right and illustrating the magnetic flux paths including a coil flux path generated by a fixed electromagnetic coil;

[0061] FIG. 9 is a schematic view of an exemplary drive structure of the invention, illustrating the magnetic flux perpendicular to the center axis and through the armature;

[0062] FIGS. 10 is a graph showing the bias forces of the drive structure superimposed along a position axis;

[0063] FIG. 11 illustrates the operation of the inventive pump for assisting the pumping of the ventricle, where trace 11A is an exemplary electrocardiogram (ECG) record of the changing potentials of the electrical field imparted by the heart, trace 11B is the left ventricular pressure, trace 11C is the aortic pressure, trace 11D is the power to the pump coils, and trace 11E is the position of the actuator plate;

[0064] FIG. 12 shows an alternative armature embodiment having three magnets;

[0065] FIG. 13 is a sectional view of an embodiment of the pump showing the magnetic field sensor;

[0066] FIG. 14 is a sectional view of an embodiment of the pump showing an embodiment of a pressure sensor;

[0067] FIG. 15 is a perspective view of an alternative embodiment pump having an external transfer portion;

[0068] FIG. 16 is a plan view of an additional alternative embodiment pump having an external transfer portion;

[0069] FIG. 17 is flowchart showing one embodiment method for the operation of the inventive pump during arrhythmia; and

[0070] FIG. 18 is a sectional view of an alternative pump embodiment having a shoe adjacent to the magnets.

[0071] Reference symbols are used in the Figures to indicate certain components, aspects or features shown therein, with reference symbols common to more than one Figure indicating like components, aspects or features shown therein.

DETAILED DESCRIPTION OF THE INVENTION

[0072] With reference first to FIG. 1A, a perspective view of a ventricular assist system **22** of the present invention is shown connected to a heart **H** of a patient **P** for the assist of a left ventricular **LV**. FIG. 1A shows a living human host patient **P** in fragmentary front elevation view, and with parts of the patient's anatomy shown in phantom or removed solely for better illustration of the salient features of the present invention. A pumping portion **20** of ventricular assist system **22** is surgically implanted into the patient's abdominal cavity **AC** and connected to the heart **H** with cannulation. The cannulation includes an inlet conduit **24** communicating blood from the patient's left ventricle **LV** into the pumping portion **20**, and an outlet conduit **26** communicating blood from the pump **20** to the patient's aorta **AO**. The pumping portion **20** of ventricular assist system **22** may also be implanted in the chest cavity of the patient with similar cannulation to the **LV** and the patient's aorta.

[0073] For purposes of explanation and without limiting the scope of the present invention, ventricular assist system **22** is illustrated assisting the left ventricle **LV** of the heart of the patient **P**. In addition to being configurable as a left ventricular assist device (LVAD), the ventricular assist system **22** may also be configured to assist the right ventricle (RVAD). Therefore, as a general matter, and except in reference to the illustrated LVAD, the source of blood for the ventricular assist system **22** may be termed the "assisted ventricle," while the destination of the pressurized blood will be designated the "arterial vessel."

[0074] Each of the conduits **24** and **26** include segments **30** and **32** extending to the left ventricle **LV** and aorta **AO**, respectively. Segment **30** and **32** are preferably flexible, and segment **30** is alternatively a rigid segment. The inlet and outlet conduits **24** and **26** are attached to the natural tissue of the ventricle and the arterial vessel by sutures to establish and maintain blood flow, and may include appropriate structure for this purpose such as a sewing ring **34** for ventricular attachment. In any of the contemplated configurations of LVAD or RVAD, the inlet conduits are anastomosed to the respective ventricle, while the outlet conduits are anastomosed to the appropriate arterial vessel, which for left ventricular assist is typically the aorta **AO** and for right ventricular assist is typically the pulmonary artery. As will be explained below, the ventricular assist system **22** includes a single ventricular anastomosis providing blood to input ports in the pumping portion **20**. Details of the conduits **24**, **26** may be shown and described in U.S. Patent No. 6,001,056, the disclosure of which is expressly incorporated herein by reference.

[0075] With continued reference to FIG. 1A, a power cable **38** extends from the pumping portion **20** to a controller **40**, a power supply **42**, such as a battery pack, and a energy transfer unit **46**, such as a transcutaneous, inductively coupled transformer, to provide energy to recharge the power supply from a source (not shown) that is external to the body of patient **P**. Other means for powering the ventricular assist system **22** are known which require a cable through the skin, and the present invention is not so limited. In addition, controller **40** and power supply **42** may be combined into a single implantable unit.

[0076] With reference to FIG. 1B, a top view of pumping portion **20** has a cut-way portion showing that the pumping portion includes a housing **44** that covers a blood pump **28**. Housing

44 is preferably rigid and is outwardly formed of a biocompatible coating such as a polymer or other suitable biocompatible material.

[0077] The description that follows will begin with a detailed discussion of the blood contacting, fluid moving portions of pump **28,** followed with details of the fluid moving aspects of the pump, and then by details of the suspension and drive aspects of the pump. The operation of the integrated system will then be presented, followed by alternative integrated pumps. Further disclosure of the various embodiments is to be found in Appendix A, attached hereto.

[0078] A first embodiment of a blood pump **200** of system **22** is seen in greater detail in FIGS. 2-5,6A and 7 with housing **44** removed, in which FIG. 2 is a perspective view and FIG. 3 is a top view of the pump, and FIGS. 4-6A and 7 are various sectional views. With reference to the perspective view of FIG. 2, blood pump **200** is connected to conduits **24** and **26**, which receive and provide blood, respectively, during pumping. Pump **200** includes an inlet portion **201**, an outlet portion **203**, and a valve **205**. More particularly, the flexible segment **30** connects to inlet port **201** and flexible segment **32** connects outlet portion **203** that includes valve **205**.

[0079] As will be described below, the pump **200** includes a pair of variable-volume chambers contained within housing **44** and operating in synchronization to provide a positive-displacement pump. The arrows in FIG. 2-4 indicate the direction of the flow through a pumping system **22**. Specifically, the flow enters pump **200** through conduit **24** into inlet portion **201**, and exits the pump at outlet portion **203** and through valve **205** into conduit **26**. Valve **205** is a unidirectional flow valve, as described below, that provides flow generally in the direction indicated by the arrows of FIGS. 2-4.

[0080] With further reference to the embodiments shown in FIGS. 2 and 4, pump **200** includes a pair of variable-volume chambers **220**, an armature or actuator plate, **210** having actuator surfaces **401,** a frame **209** partly enclosing the chambers and actuator plate and retaining a pair of coils **207**, and four pairs of springs **231**. Pump **200** also includes an electromagnetic structure **800** powered by coils **207** as shown with reference to FIG. 8, and described subsequently. As such pump **200** is conveniently discussed with regards to a center, or polar, axis **C** through the center of coils **207** and a midplane **M** between coils **207**, both of which are shown in FIGS. 4 and 8. Importantly, the movement of armature **210** within frame **209** affects

changes in the volume of chambers **220**. In the embodiment of pump **200**, the volumes are changed through the contact of chambers **220** with actuator surfaces **401** of armature **210**, and with frame **209** and coils **207**, though the scope of the present invention is not limited by this structure. Since armature **210** can move within frame **209** to actuate a change in volume of chambers **220** it is alternatively referred to herein as either an "actuator plate" or an "armature." While actuator plate **210** surrounds the electromagnetic structure of armature **210**, the present invention is not so limited. More generally, pump **28** provides pumping action through the interaction of a pair of variable-volume chambers and an electromagnetic structure having an armature, and the actuator plate does not necessarily surround the electromagnetic structure of the armature. In an alternate embodiment (not shown) the actuator plate is not surrounded by the electromagnetic structure of the armature, instead the armature is coupled to the actuator plate.

[0081] As is shown in FIGS. 2 and 4, frame **209** is a box-like structure that includes a pair of inward facing surfaces **413 (413a, 413b)**, four pairs of surfaces **235** and four pairs actuator plate stops **233**. Frame **209** is part of electromagnetic structure **800** as is discussed below, and as such is formed from a soft magnetic material. The box-like structure allows frame **209** to provide these functions while minimizing the weight of pump **200**. Coils **207** are retained in frame **209** and present inward facing surfaces **403 (403a, 403b)**. Surfaces **403** and **413** together form inward facing surfaces **404**. Specifically, surface **403a** and **413b** together define surface **404a**, and surface **403b** and **413b** together define surface **404b**.

[0082] As shown best in FIG. 4, the pair of chambers **220** includes a first, or transfer, chamber **220a** and a second, or pump, chamber **220b**. As shown in the Figures, common features of the pair of chambers **220** are indicated with the ending "a" or "b" for the first or second chamber, respectively. Specifically, each of the pair of chambers **220 (220a, 220b)** includes a flexible sac **221 (221a, 221b)**, the internal volume of which defines a chamber volume, and a pair of ports **223 (223a, 223b)** and **225 (225a, 225b)** to the internal volume. In addition, each of the pair of chambers **220** has an outwardly facing surface **227 (227a, 227b)** and an inwardly facing surface **229 (229a, 229b)**. Inward surfaces 404 are adjacent to corresponding ones of the outwardly facing surfaces **227** and provide support for chambers **220.** Fluid inlets and outlets to chambers **220** are provided at inlet portion **201**, which is connected to port **223a**,

and at outlet portion **203**, which is connected to port **225b**. Fluid communication between each of the pairs of chambers **220** are provided by a transfer portion **301**. As is best seen in FIGS. 4 and 5B, transfer portion **301** connects chambers **220** at ports **225a** and **223b**, and has an internal transfer valve **303**.

[0083] Each of the pair of flexible sacs **221** are preferably configured as relatively flat disk-shaped bags. It should be noted that other sac configurations are possible within the understanding of one skilled in the art, and also that variable-volume chambers may be defined by structures other than flexible sacs, such as piston-cylinder couples, moveable walls, etc. A number of features of the present invention can thus be transferred to other fluid propulsion arrangements, though the use of dual flexible sacs provides a number of significant advantages and is thus preferred.

[0084] With reference to FIGS. 4, 5A and 6A, actuator plate **210** is a generally planar structure having the pair of spaced apart, outer actuator surfaces **401** (shown as **401a** and **401b**) and four tabs **211** that are disposed about the actuator plate. Preferably, the tabs are arranged equidistant from and symmetrically disposed about the actuator. Actuator plate **210** is positioned within frame **209** such that tabs **211** can move in a direction generally aligned with and perpendicular to center axis **C** and between actuator plate stops **233**. Actuator plate **210** also has a passageway **417** through which transfer portion **301** passes from chamber **220a** to **220b**.

[0085] With further reference to FIG. 4, the pair of chambers **220** is disposed on either side of actuator plate **210** and within frame **209**. Specifically, the pair of sacs **221** are disposed in parallel and spaced apart by actuator plate **210**, with actuator surface **401a** of the actuator plate contacting inwardly facing surface **229a** of first sac **221a**, and actuator surface **401b** of the actuator plate contacting inwardly facing surface **229b** of second sac **221b**. The outward facing surfaces **227** of sacs **221** are also in contact with corresponding ones of inward facing surfaces **404**. The inwardly-facing surfaces **229** and the outwardly facing surface **227** of each sac **221** are preferably affixed to actuator plate **210** and surfaces **404** with, for example, adhesive. With further reference to FIG. 5A, pump **28** of the present invention may include plastic housing rings **501** disposed between sacs **221** and frame **209** to provide additional support to sacs **221**, and to

direct movement of the sacs during pumping to preferred portions of the sacs, for example, those areas that are adjacent to but not in contact with actuator plate **210**.

[0086] Each one of spring **231** spans the distance from one side of one of tabs **211** to one of surfaces **235**. Pump **200** thus provides for the suspension of actuator plate **210** within frame **209** by pairs of springs **231**. As described below, the suspension of actuator plate **210** by springs **231** stabilizes the motion of the actuator plate in frame **209**, in that tilting of the plate during this motion is corrected by the righting force of springs **231**. In addition to suspending actuator plate **210** within frame **209**, springs **231** are used to store and release energy to the drive, as discussed subsequently. The position of actuator plate **210** within frame **209** is conveniently discussed with reference to a distance indicated as **x** representing a displacement of a midplane **MP** of the actuator plate **210**, as shown in FIG. 4 and 8. Actuator plate **210** has a maximum travel of **x** = S/2 on either side of midplane **M**. Since the pump has room for sacs **221** and blood between the actuator plate **210** and frame **209,** the maximum travel **S**/2 is less than the gap **g**.

[0087] Movement of actuator plate **210** within frame **209** deforms and changes the volume of individual ones of the pair of chambers **220**. However, the total volume of the pair of chambers **220** remains constant as the actuator plate moves due to the attachment of chambers **220** to both frame **209** and actuator plate **210**. The ejection volume of each of the chambers **220** is no more, and preferably less than, the ejection volume of the ventricle being assisted. For example, in the illustrated pump of FIG. 2, the ejection volume of each of the chambers **220** is on the order of the ejection volume of the left ventricle **LV** shown in FIG. 1A. The ejection volume of each of the chambers **220** is preferably less than the expected ejection volume of ejected blood, for example from 40 to 60 ml. To accept and pump the ejection volume of the ventricle in full with chambers **220**, the blood pump **28** has a drive system that nominally pumps the chambers **220** once for each beat of the heart **H** and provides a flow of blood during such pumping. The drive system displaces the armature **210** to alternately compress each of the pair of chambers **220**. The range of motion of armature **210**, and thus the minimum and maximum volumes of chambers **220** is determined by surfaces **235**, or preferably by the placement of stops **233**, which both control the stroke range of pump **200** and provide damping in case of excessive armature motion.

[0088] Each of the inlet and outlet conduits **24, 26** extend generally tangentially from the cylindrical pumping portion **20**, as is best seen in FIGS. 2 and 3. The configuration of ports **225a** and **225b** are disposed tangentially with respect to the disk-shaped sacs **221a** and **221b**. Likewise, ports **223a** and **223b** are tangential to the sacs **221a** and **221b**. The tangential orientation of the ports **223** and **225** is believed to most effectively fill and flush blood to and from the chambers **220**. The housing **44** also includes apertures (not shown) for receiving ports **223** and **225** that are sealed about the ports to prevent fluid seepage therebetween. Details of various aspects of the sac shape, connectors and seals are shown and described in U.S. Pat. No. 5,511,958, the disclosure of which is expressly incorporated herein by reference.

[0089] The shape of the chambers **220** during the movement of actuator plate **210** within frame **209** is given by the limits of actuator plate motion imposed by tabs **211** and actuator plate stops **233**, and the shape of the surfaces to which it is attached, specifically the matching surfaces **404a** and **401a** of sac **221a**, and surfaces **404b** and **401b** of sac **221b**. Preferably, the volumes defined by sacs **221** also facilitate the filling and flushing of blood, and avoid fully compressing the volumes and possibly damaging blood therein. As described below, several of these surfaces also perform functions associated with the electromagnetic drive, and thus necessarily have magnetic properties described below. Additional material required to shape surfaces **401a**, **401b**, and **404** to achieve proper flow through pump **200** may thus be provided through the use of suitable non-magnetic materials. It is preferable that these materials are light weight, and thus appropriate materials include, but are not limited to plastics, epoxies, or lightweight nonmagnetic metals, such as aluminum.

[0090] As seen in FIG. 4, outlet portion **203** includes valve **205** having a flap structure **405** and transfer portion **301** includes valve **303**. The valves **205** and **303** enable the positive-displacement pump to function as will be explained below. The structure **405** is desirably a valve formed from polymeric or xenograft tissues, such as porcine aortic valves, although the present invention is not so limited. Details of various aspects of tissue valves and connections to conduits are shown and described in U.S. Pat. Nos. 5,599,173, 5,810,708 and 6,102,845 the disclosures of which are expressly incorporated herein by reference.

[0091] Valve **303** is a tilting-disk type of valve, where a disk **304** can tilt between an upwards position, as shown in the sectional view of FIGS. 4 and 5B to allow flow upwards through valve **303**, and a horizontal position (not shown) to stop the flow through transfer portion **310**. It is preferred that, when valve **303** is open, transfer portion **301** provides for the smooth flow of blood from chamber **220a** to chamber **220b**. As described subsequently, inlet and outlet conduits **24, 26** extend generally tangentially from the sacs **221**, resulting in circulating flow in each sac about the central axis **C** in a plane parallel to midplane **MP** of the actuator plate **210**. To accommodate the flow between sacs, it is preferred that transfer port **301** is angled by an angle θ with respect to the midplane **M,** as indicated in FIG. 5B. As an alternative embodiment, a bileaflet mechanical valve could be used in place of the single leaflet valve **303** described above. Another alternative embodiment armature **210'** is shown in FIG. 6B as having two transfer ports **301** to facilitate flow between chambers **220**.

[0092] Alternatively, a tissue valve could be used for valve **303**. Since valve **303** is interior to pump **200**, the use of a tissue valve would require that the pump be filled with a preservative, such as glutaraldehyde.

[0093] As another alternative embodiment, one or more conduits **32** and outlet portion **203** may be integrally formed of a suitable polymer, for example, with the valves also being formed therein of the same or a different material. Since valve structure **303** is internal to pump **200**, it is more difficult to provide xenograph valves at the time of transplant, and so polymeric valves are preferable for the internal valve.

[0094] In another alternative embodiment illustrated in FIG. 18, a shoe **1801** is provided at the periphery of the magnets **1803**. Shoe **1801** provides the electromagnetic advantages noted in the '601 patent. A further advantage of the shoe is that it permits part of the flexing region of the sacs **1805** to be incorporated within the thickness of the armature, against shoe **1801** and so reduces the overall thickness of the pump .

Spring Suspension

[0095] Pump **28** of the present invention also includes a suspension to stabilize the motion of actuator plate **210** within the pump, such that actuator plate remains in an orientation generally parallel to the pair of sacs **221**, and such that it works in cooperation with the electromagnetic

drive, as described below. The positions and spring constants of springs **231** are preferably selected such that the forces on actuator plate **210** results in a net righting force on the actuator plate that permits it to move back and forth within the frame without tilting, that is along and generally perpendicular to central axis **C,** as shown in FIG. 4.

[0096] While some of the features noted in the previous paragraph have similarities to the drive disclosed in the '601 patent, the spring suspension system has several features not found in the '601 patent. In particular, while the pump of the '601 patent uses springs in conjunction to an electromagnetic drive that is similar to that of the inventive pump, the springs of the ' 601 patent cooperated with the electromagnetic drive system of the '601 patent to balance the forces about midplane **M** and thus neutrally suspends the armature between the chambers. In contrast, springs **231** of the present invention provide a "spring force" on the actuator plate that is towards the high-pressure pump chamber. The bias force is useful in that it allows the springs to store and deliver energy from the electromagnetic drive system to provide better utilization of the pump components, and to reduce the pump size and consumption of electricity.

[0097] Springs **231** are preferably configured to be linear with a total spring constant k, and having a position offset that, in conjunction with the axial force produced by the permanent magnets, produces a bias force towards chamber **220b** irrespective of the placement of actuator plate **210**. Specifically, the springs are positioned so that their net force on actuator plate **210** is zero at a distance h from midplane **M**, resulting in a spring force F_S of:

$$F_S = k\,(h - x)\,. \tag{1}$$

[0098] Springs **231** are in compression throughout the travel of actuator plate **210,** thus reducing fatigue in the spring from the reciprocating load, and simplifies spring retention. Shims, adjusting screws, and/or selected spring sizes may alternatively be used to level the actuator plate **210** during pump fabrication, and, as described below, to correctly balance the magnet force, and to set the proper eject assist pressure. In addition, each pair of spring produces the same force at the same distance from center line **C.**

[0099] One embodiment of the suspension is illustrated for pump **200.** Forces on actuator plate **210** within frame **209** are provided by four pairs of springs **231** that are disposed at the same approximate radial position about the periphery of the actuator plate at tabs **211**. Each pair

of springs **231** is positioned with one on each side of tab **211** of actuator plate **210**, and between surface **235** of frame **209**. The clearances between surfaces **235** and the adjacent tabs **211** are all the same. The spring forces of springs **231** are selected so that, with actuator plate **210** perpendicular to axis **C**, each of the pairs of springs **231** each exert the same force on symmetrically disposed tabs **211,** and that the total force of all of springs **231** with the actuator plate so oriented is parallel to axis **C**. Any motion actuator plate **210** that is not perpendicular will result in displaced spring forces that will exert a moment on the actuator plate and will tend to force it back to a perpendicular orientation.

[00100] Exemplary springs **231** are shown as helical compression springs, any spring configuration that similarly resists displacement of the armature **210** may be used, for example, leaf springs or one large spring on the side of one of the pairs of chambers **220** such as a large diameter coil spring. It is preferred that each of the exemplary springs **231** are always in compression to reduce fatigue on the springs, simplify retention, and avoid separation and subsequent contact of springs **231,** frame **209**, and armature **210** during armature motion.

VAD Operation

[00101] As mentioned above, the drive system (a preferred embodiment of which is described below) displaces the armature, or actuator plate, **210** to alternately compress each variable-volume chamber **221**. FIGS. 7A to 7F present schematic views of one configuration of pumping chambers of the present invention. In accordance with the series flow blood pump **28** exemplified in FIGS. 2-6A, blood from the ventricle is initially pumped to the first chamber **220a** through inlet conduit **24**. The drive system is first activated in a 'pump stroke' to displace armature **210** to the right as shown by the arrow in FIG. 7A, thereby ejecting blood received within second chamber **220b** through valve **205**, into outlet conduit **26**, and through outlet segment **32** for delivery to the aorta. During the pump stroke of armature **210**, valve **303** prevents blood from flowing through transfer portion **301**. In addition, pump **200** actively fills during the power stroke since the first chamber **220a** is expanding, thereby drawing oxygenated blood through the inlet conduit **24** from the left ventricle **LV** into the left chamber as shown in FIG. 7B. During the power stroke, blood is thus flowing though both of conduits **24** and **26,** as well as flowing into chamber **220a** and out of chamber **220b**. At the end of the pump stroke as

shown in FIG. 7C with the armature **210** positioned to the right, the first chamber **220a** is filled with oxygenated blood from the left ventricle, and the second chamber **220b** is compressed to a minimum volume. At the end of the power stroke, valve **205** will close, and pumping ceases. As described below, there are some inertial effects of the flowing blood that may result in continued flow for a brief period of time after the end of the power stroke (this is referred to as dynamic ejection, as described below).

[00102] Preferably soon after the end of the power stroke, the drive system is activated to execute a 'transfer stroke' to move the armature **210** to the left as shown by the arrows in FIGS. 7D and 7E, thereby drawing blood from the first chamber **220a** into the second chamber **220b** via the transfer portion **301**. The outlet valve **205** prevents blood in the aorta or the outlet conduit **26** from being drawn back into the second chamber **220b**. In addition to left ventricular pressure, the low pressure within the second chamber **220b** caused by the expansion of the chamber ensures that blood within the first chamber **220a** enters the second chamber **220b** and is not ejected back into the inlet conduit **24**. Thus during the transfer stroke, there is no net flow through pump **200.** At the end of the transfer stroke as shown in FIG. 7F with the armature **210** positioned to the left, the second chamber **220b** is filled with oxygenated blood from the left ventricle, and the first chamber **220a** is compressed to a minimum volume. The pump stroke illustrated in FIGS. 7A-7C and the transfer stroke illustrated in FIGS. 7D-7F may be repeated in accordance with the exemplary methodology of the invention described below.

[00103] In general, different amounts of power are required by armature **210** to execute the transfer stroke and the pump stroke. Specifically, the transfer stroke transfers blood from chamber **220a** to chamber **220b** with no net flow through pump **200**, while the pump stroke consumes energy in raising the pressure in chamber **220b** and pumping fluid from the pump.

Preferred Electromagnetic Drive System

[00104] The preferred electromagnetic drive system of the invention will now be described with reference to FIGS. 4, and 7-9. In particular, FIG. 8A is a schematic view of an exemplary drive structure of the invention, illustrating a magnetic flux path generated by a magnet on an armature (shown in an equilibrium position) , FIG. 8B is a view similar to that of FIG. 8A, showing the armature displaced to the right and being driven to the left and illustrating the

magnetic flux path including a coil flux path generated by a fixed electromagnetic coil, FIG. 8C is a view similar to that of FIG. 8A, showing the armature displaced to the left and being driven to the right and illustrating the magnetic flux path including a coil flux path generated by a fixed electromagnetic coil, and FIG. 9 is a schematic view of an exemplary drive structure of the invention, illustrating the magnetic flux perpendicular to the center axis and through the armature.

[00105] For the purposes of this description, the drive system includes an electromagnetic structure **800** having center axis **C** and midplane **M**. With reference to FIGS. 4, 8, and 9, electromagnetic structure **800** includes frame **209** in which is mounted the pair of electrically-conductive coils **207**, including a first coil **207a** and a second coil **207b**, and armature **210**. As shown in FIGS. 4 and 8, the coils **207** are disposed in a spaced relationship within the frame **209** on opposite axial sides of the armature **210**. Coils **207** may be configured as annular rings having trapezoidal, rectangular or other shapes to best utilize the space within pump **200** for producing a field as described herein with a minimum weight. The coils **207a** and **207b** are powered with approximately equal values of amp-turns (NI) to generate a magnetic flux Φ_c defining a pair of poles **801**, including a first **801a** and a second pole **801b**, as shown in FIGS. 8B and 8C. Poles **801** are generally contained within frame **209** and present surfaces **413** to the interior of the frame. The polarity of the electric circuit through the coils **207** determines the magnetic flux direction as shown in FIGS. 8B and 8C and, thus, the physical influence on the armature **210**.

[00106] The armature **210** is disposed within the frame **209** between the poles **801** and the magnets **601** positioned between the coils **207**. When the armature **210** is centered between the poles **801** at the midplane **M**, a gap **g** is defined on either side of the armature, as shown in FIG. 8A. In addition, an annular gap **a** having a substantially constant radial dimension is defined between the radially outermost surface of the armature **210** and an inner surface of the frame **209**.

[00107] With reference to FIGS. 4 and 8, each of the poles **801** defines an inwardly facing surface **413**, generally within the annular coils **207**, disposed normal to the central axis **C** and facing the armature **210**. The frame **209** includes a pair of centrally-located, outwardly-facing conical cavities **521a** and **521b** so that the poles **801** comprise annular regions **415** that transition

along the cylindrical cavities **521** to the area of the inwardly facing surfaces **413**. In this manner, the overall mass of the device is reduced which helps facilitate patient acceptability and comfort. Alternative embodiments (not shown) include cavities **521** that are cylindrical or that have other symmetric shapes about center line **C**.

[00108] As is best seen in the sectional view of FIGS. 4-6A armature **210** is a generally planar structure that includes a central core **407** of a magnetically permeable material and two symmetrically placed magnets shown as a pair of magnets **601** about the central core. Armature **201** also includes a non-magnetic material **701** that fills out the remainder of the actuator plate structure, specifically the pair of spaced apart, actuator surfaces **401** and the four tabs **211** about the periphery of the armature. The pair of magnets **601** and magnetically permeable portion **407** are situated so as to provide a magnetic flux shown as paths Φ_{Ba} and Φ_{Bb}. As is seen in the top view of FIG. 9, the return path **901** of magnetic flux path Φ_{Ba}, Φ_{Bb} is through frame **209** and near magnets **601**. The springs **231** may also provide a return path for the magnetic flux.

[00109] The magnetic flux path Φ_{Ba}, Φ_{Bb} tends to create an instability of armature **210** in a central position between the two variable-volume chambers **220**, due to the attraction of magnets **601** to frame **209.** The instability tends to bias armature **210** toward one or the other variable-volume chamber **220** upon a slight displacement in that direction. This bias produces a force on armature **210**, in the absence of any energization of coils **207** that varies with increasing displacement from midplane **M** that is referred to herein as the "magnetic force."

[00110] Also shown in FIGS. 4 and 6A, armature **210** has a diamond-shaped hollow center **409** in core **407**, which reduces the weight of the pump **28**. More to the point, the hollow center **409** reduces the mass of armature **210**. In addition, the reduced mass also results in a reduced power (and battery size) needed to displace it, and in turn reduces the size the electromagnetic drive components. The entire device can thus be reduced in size to further facilitate successful implantation.

[00111] The use of a pair of magnets **601** in armature **210** is an inexpensive alternative to symmetrical magnets, such as those of the '601 patent, for example. In addition, magnets **601** take up less space in armature **210**, allowing for other uses for the armature, such as by placing

transfer portion **301** through the armature. The present invention includes electromagnetic structures having more than two magnets, such as three or more magnets, as well as other spring arrangements for stabilizing armature movement. It is preferred that the magnets be placed with like poles towards center line **C**, and that they be symmetrically placed about the center line to keep the armature balanced. FIG. 12 shows an alternative embodiment of a pump **1200** having an armature **1200** with three magnets **1201**, surfaces **1205** for receiving springs on either side of each magnet, and a transfer port **1203**.

Electromagnetic Drive System

[00112] Radially polarized magnets **601** generate bias flux Φ_B that follows a closed magnetic circuit including the frame **209**, a respective one of the poles **801**, a respective one of the gaps **g**, and the armature **210**. Bias flux Φ_B is shown as Φ_{Ba} for the flux that goes about coil **207a** and as Φ_{Bb} for the flux that goes about coil **207b**. Advantageously, electromagnetic flux Φ_C generated by the coils **207** does not travel a path through the magnets **207**, but instead traverses around the outside of the frame **209** and through the poles **801**, gap **g**, and armature **210**; accordingly, the bias flux Φ_B remains substantially constant and predictable. As the bias flux Φ_B is substantially constant, the magnet **601** is not subject to depolarization, which is discussed in more detail below.

[00113] The armature **210** moves either towards pole **801b** as shown in FIG. 8B or towards pole **801a** as shown in FIG. 8C by a distance indicated as **x**. With particular reference to FIG. 8B, when electrically activated, the coils **207** generate coil flux Φ_C which follows a path including the frame **209**, one of the poles **801a** or **801b**, one of the gaps (either [**g**+**x**] or [**g**-**x**]), the armature **210**, the other gap, the other pole, and the frame.

[00114] Details of electromagnetic structure **800** are presented in the '601 patent. In particular, it is preferred that the electromagnetic structure **800** is a linear magnetic structure. Following the presentation of the '601 patent, the electromagnetic structure **800** is configured so that:

(a) the coil flux Φ_C follows a substantially closed path to make efficient use of the magnets **601**;

(b) the total bias flux Φ_B is substantially constant to eliminate depolarization of the

magnets **601**, which generates the bias flux;

(c) a relatively low magnetic field intensity (H) over a relatively large area A of the poles **801** significantly reduces the need for high-precision components; and

(d) energy conversion is linear to simplify optimization and control.

[00115] In particular, electromagnetic structure **800** is configured so that the maximum values of the fluxes Φ_{Ba} and Φ_{Bb} traversing between the armature **210** and the poles **801** of FIG. 8B (and the connected parts of electromagnetic structure **800**) are below the magnetic saturation level of the armature **210** and poles **801**; accordingly, the magnetostatic equivalent circuit of electromagnetic structure **800** is linear. Also, electromagnetic structure **800** is preferentially configured so that fringing magnetic fields located around the poles **801** and the annular gap are insignificant. One way for the resulting magnetostatic equivalent circuit to be approximately linear is for the poles **801** to preferably have a relatively large pole area A_{pole}. Accordingly, the magnetic flux density (B) is preferably on the order of 0.5 tesla (T) for an exemplary blood pump embodiment. A magnetic flux density of this magnitude is significantly less than the magnetic flux density saturation (B_{SAT}) of core material used in the armature **210** and the poles **801**. Therefore, exemplary armature **210** may have a hollow center **409** (as shown in FIG. 6A and 6B) to reduce the weight of the overall electromagnetic structure **800**.

[00116] As the electromagnetic system is linear, the fields can be treated separately and superimposed. As presented in the '601 patent, accordingly, the bias fluxes Φ_{Ba} and Φ_{Bb} and the coil flux Φ_C may be calculated separately and, with no current through coils **207** (I = 0) the total energy and force on armature **210** along center axis **C** is:

$$W_b = \Phi_B^2(g^2 - x^2)/4\ \mu_o\ g\ A_{pole};\ \text{and}$$
$$F_b = -\partial W_b/\partial x\ = \Phi_B^2 x/2\ \mu_o\ g\ A_{pole}, \qquad (2)$$

where μ_o is the permeability of free space ($4\pi 10^{-7}$ in SI units). Accordingly, as the armature **210** moves towards pole **801a**, the bias flux Φ_B shifts from left to right, with the total flux Φ_B remaining constant. As energy W and force F vary with Φ_B^2, the shift in force F_b is marked. This phenomenon is illustrated in FIG. 8B. The shift in the force F_b constitutes a negative spring that can be used to balance the suspension system provided by springs **213**, which will be

discussed in detail below. As shown in the equation for W_b and F_b, the energy and force are both independent of coil current.

[00117] Magnets **601** are preferably made from a material having a high energy density and a low marginal permeability, for example, rare earth material such as samarium cobalt (SmCo) or neodymium iron (NdFe). Accordingly, the magnets **601** as described above are a source of flux. Therefore, the bias flux Φ_B is constant in the magnets **601**, and all of the flux Φ_C generated by the coils **207** traverses the loop shown by the lines in FIG. 8B, including the frame **209**, the pole **801a**, the gap **(g+x)**, the armature **210**, the gap **(g-x)**, the pole **801b**, and the frame **209**.

[00118] The force contributed by the coil current I from a coil having N turns is calculated from the total energies in the left and right gaps (holding the bias fluxes $\mathbf{\Phi_{Ba}}$ and $\mathbf{\Phi_{Bb}}$ constant):

$$F_C = - N\, I\, \Phi_B/2g \ , \tag{3}$$

The coil force F_C is independent of displacement x and area A and is linear in flux Φ_B. Accordingly, the following total electromagnetic force F_{EM} equation results from the force F_B and the coil force F_C respectively represented by Equations 2 and 3:

$$F_{EM} = F_b + F_C = \Phi_B^2 x/2\, \mu_o\, g\, A - N\, I\, \Phi_B/2g \tag{4}$$

[00119] Equation 4 enables wide design latitude through varying the flux. Φ_B and the area A of the poles **801** as the area A_{pole} does not contribute to the coil force F_C. For example, it is desirable for the value of the flux Φ_B to be large as flux directly determines the coil force F_C generated by a given coil current I. For a given coil geometry, force F_C is proportional to the product of number of turns N and coil current I (that is, $F_C \propto NI$), and power dissipation P_{Diss} is as follows:

$$P_{Diss} = I^2 R \propto (NI)^2 \tag{5}$$

Accordingly, efficiency may be improved by using a high flux Φ_B and a modest NI. To prevent the large flux Φ_B from developing too much force F_b, which is balanced by springs **231** as described below, the poles **801** preferably have a relatively large area A_{pole}. A large pole area A_{pole}, in turn, implies a low value of magnetic flux density B; accordingly, the effect of fringing fields is minimized or substantially eliminated.

Electromagnetic Drive System and Energy Storage

[00120] The approximate forces acting on actuator plate **210**, and the resulting operation of the combined drive and energy storage mechanisms, will now be illustrated for ideal magnets and spring forces. The total drive and energy storage force, F_{total}, acting on actuator plate **210** is given by the sum of the electromagnetic force of Equation (4) and the springs force of Equation (1) as:

$$F_{total} = F_b + F_S + F_C \qquad (6)$$

The first two terms of Equation 6 is a net bias force F_{bias} that is independent of coil current I:

$$F_{bias} = F_b + F_S = [\Phi_B^2 x/2\ \mu_o\ g\ A_{pole}] + [k\ (h - x)] \qquad (7)$$

If the spring constant k and electromagnetic drive constants Φ_B' g, and A_{pole} are selected such that:

$$k = \Phi_B^2/2\ \mu_o\ g\ A_{pole}\ , \qquad (8)$$

then the net bias force F_{bias} is:

$$F_{bias} = k\ h = h\ \Phi_B^2/2\ \mu_o\ g\ A_{pole}\ , \qquad (9)$$

and is thus also independent of the position of actuator plate **210**. The total force F_{total} is:

$$F_{total} = F_{bias} + F_C = h\ \Phi_B^2/2\ \mu_o\ g\ A_{pole}\ -\ N\ I\ \Phi_B/2g, \qquad (10)$$

The total force is thus independent of the position of actuator plate **210**, and is the sum of a net bias force that is independent of coil current I and a coil force that depends linearly on the coil current I.

[00121] The sum of the bias forces is shown graphically in FIG. 10 as a graph of the bias forces. The spring force F_S resulting from the force of suspension springs **231** on the actuator plate **210**, and the magnetic force, F_b, resulting from of the attraction of armature **407** towards surfaces (stator pole) **413** are selected through Equation (8) to result in position independent bias force. Specifically, the springs **231** and the structure **800** are selected such that the sum of the spring force opposes the magnetic force and such that the sum of the spring force and magnetic force is a force towards chamber **220b** that is a constant bias force approximately independent of the position of armature **210** in frame **209.**

[00122] It is preferred that the bias force produces a pressure (given by the total force F_{total} divided by the actuator plate area, A_{AP}) in chamber **220b** that allow actuator plate **201** to remain between actuator stops **233** under the action of the aortic and ventricular pressures, and that does not permit either of one-way valves **205** or **303** to open between the end of one systole and the beginning of the next. In preferred embodiments, pressure F_{bias}/A_{AP} is typically 40 to 50 torr for left ventricular assist, and 20 to 40 torr for right ventricular assist, with the remainder of the pressure delivered by the force F_C.

[00123] In general, the ability to control the pump pressure and timing through the coil current allows for many advantages. The pump can be run at a rate that is on the order of the physiological time of a beating heart, reducing the peak pressure in comparison with other types of drives, and thus improving the lifetime of moving parts, such as the one-way valves. The controllability of the pressure according to the applied coil current also allows the pressure to be tailored during the pump stroke, allowing for example, an increased pump rate near the end of the pump stroke.

[00124] In one embodiment, pumping occurs by imposing a coil current that alternates direction between strokes ($I_{pump} = - I_{transfer}$). In addition, the times over which the power and transfer strokes occur are approximately the same such that the total power delivered to coils **207** during the transfer stroke and the power stroke is the same, optimizing the use of electrical and electromagnetic components. During the transfer stroke, electromagnetic power is transferred to armature **210** to transfer blood from chamber **210b** to chamber **210a**, and to compress and thus store energy in springs **231**. During the power stroke, electromagnetic power is transferred to armature **210** and the expanding springs **231** release stored energy to augment the electromagnetic power. The springs thus serve to store energy and effectively load level the electromagnetic drive energy, and the electromagnetic drive operates at one-half the average pumping power, better utilizing power and pump components.

[00125] During the pump stroke, valve **303** is closed, and the motion of actuator plate **210** draws blood from inlet conduit **24** into chamber **220a** and pushes blood from chamber **220b** into outlet conduit **26**. Immediately at the end of the pump stroke, actuator plate **210** stops. Because of the momentum of blood flow on either side of the actuator plate, there is a tendency for valve

303 to momentarily open at the end of the pump stroke, allowing for the "dynamic ejection" of blood after the end of the pump stroke. As a result of valve **303** opening and the momentum of blood on either side of actuator plate **210**, the volume of blood delivered for each pump stroke can be larger than the volume of chamber **220b.** Dynamic ejection thus allows for the use of a pump having a volume that is less than the volume of blood to be pumped on each stroke.

[00126] The magnitude of dynamic ejection is proportional to the pressure across valve **303** at the end of the pump stroke. During the power stroke, a force $F_{pump} = (h\ \Phi_B^2/2\ \mu_o\ g\ A_{pole} + N\ I\ \Phi_B/2)$ is generated by the drive and recovery of energy from the springs to give a pump pressure, P_{pump} of:

$$P_{pump} = F_{pump}/A_{AP} = (h\ \Phi_B^2/2\ \mu_o\ g\ A_{pole} + N\ I\ \Phi_B/2)/A_{AP}\ . \qquad (11)$$

The amount of dissipation in the coils is proportional to the square of the coil current, and thus the energy efficiency of dynamic ejection is limited by dissipation.

[00127] Pump **200** will thus develop a positive pressure across the actuator plate **210**, and open the transfer valve **303**, allowing continuing through flow in excess of the static capacity of the pump. This does not, however, imply two opening and closing cycles for this valve each stroke, because, as discussed below, the control algorithm preferably begins the transfer stroke immediately at the end of the pump stroke. The dynamic flow then decelerates as its kinetic energy is extracted to continue moving blood against the afterload.

[00128] In another embodiment, the coil currents and stroke times for pumping and transfer are not *a priori* selected to have the same magnitude, but are selected to provide a high overall system efficiency. By adjusting the currents and stroke times to eject and transfer blood with the time between sequential pump cycles, the total energy dissipation can be reduced with a resulting increase in system efficiency. In one embodiment, the pumping and inter-pump transfer flow rates are selected to minimize dissipation in the nominal case where extra time is available between strokes. One particular embodiment provides a pumping flow rate of 300-400 ml/sec, while the minimum flow rate needed to keep up with the cardiac cycle and allow for the controlling "wait" interval between the transfer and pump strokes is in the range of the 250-300 ml/sec.

Ventricular Assist System—Control and Coordination with Heart under Normal Conditions

[00129] Referencing FIGS. 11 and taking the foregoing into consideration, it is advantageous from an energy point of view to accept and pump blood ejected by the assisted ventricle during systole (i.e., ventricular contraction) as rapidly as is consistent with fluid flow considerations, and to stop pumping during diastole (i.e., ventricular dilation).

[00130] As shown in FIG. 11, trace 11A is an exemplary electrocardiogram (ECG) record of the changing potentials of the electrical field imparted by the heart, trace 11B is the left ventricular pressure, and trace 11C is the aortic pressure. To briefly explain the cycle of systole and diastole, the ECG signal shown in FIG. 11 illustrates a series of points representing various muscle contractions within the heart. Generally, blood is received in the left ventricle and it fills during the T-Q period. Then, during the period Q-T, the left ventricle contracts and expels blood into the aorta (systole). Accordingly, the pressure diagram in FIG. 11 shows the left ventricular pressure rapidly increasing during the spike indicated at R on the ECG signal. For the purposes of this description, ventricular systole may be considered as occurring between the R and T points on the ECG wave. The pressure in the aorta is a maximum at the end of the R-T period and generally varies with a smaller pressure variation and more smoothly than the ventricular pressure.

[00131] Also shown in FIG. 11 is trace 11D showing the power to the pump coils, and trace 11E showing the position of the actuator plate **210**. When the heart enters systole (e.g., at the beginning of the QRS complex of the ECG), the pressure within the **LV** begins to rise. The pressure in chamber **220a**, which is in fluid communication with the **LV** through conduit **24**, will also begin to rise as indicated by trace 11B. This slight increase in pressure, augmented by springs **231** will cause a slight movement of actuator plate **210** towards chamber **220b**. A signal indicative of this movement, sensed as discussed subsequently, is assumed to indicate the beginning of systole.

[00132] According to a preferred control strategy, controller **40** receives the indication of movement of actuator plate **210** at a time t_1 and triggers pump **220** to assist the ventricle by activating coils **207** to a current I for a time t_{pump} as indicated in trace 11D, and thus move the armature **210** towards chamber **220b** to pump blood into the aorta **AO,** and to accept blood from the **LV** into chamber **220a**. If the **LV** is nearly empty, the pressure rise in chamber **220a** will not

be sufficient to move actuator plate **210**, and controller **40** will not initiate the pump stroke. Upon completion of the pump stroke, controller **40** causes the current flow through coils **207** to be reversed, initiating the transfer stroke. At the end of the transfer stroke, the current to the coils is reduced to zero as the pump waits for the next increase of systolic pressure and a repeat of the pump stroke.

[00133] If the patient's physiologic state is such that the LV stroke volume is equal to the stroke volume of the VAD, then the phasing between the heart and the VAD will be as illustrated in Fig. 11 on every beat, and the pump rate will be equal to the heart rate. In the general case, however, the LV stroke volume may be smaller or larger than the VAD stroke volume. If the LV stroke volume is smaller than the VAD stroke volume, the volume absorbed into the transfer chamber during each pumping stroke will be greater than the LV stroke volume. Average LV volume will decrease, resulting in a general decrease in LV pressure. If the **LV** is nearly empty, the pressure rise in chamber **220a** during the wait period will not be sufficient to move actuator plate **210**, and controller **40** will not initiate the pump stroke. The average pump rate will thereby be lower than the heart rate, such that the pump output (VAD stroke volume times average pump rate) equals the cardiac output (LV stroke volume time heart rate).

[00134] Conversely, if the LV stroke volume is larger than the VAD stroke volume, the VAD can not absorb the entire LV stroke volume into the transfer chamber during the pumping stroke, and the subsequent transfer stroke will begin before the end of LV systole. If the end of the transfer stroke is reached while the pressure in the **LV** is still high, a second pump stroke/transfer stroke will be initiated without waiting for the start of the next LV systole. The average pump rate will thereby be higher than the heart rate, such that the pump output (VAD stroke volume times average pump rate) equals the cardiac output (LV stroke volume time heart rate). Thus pump **28** is said herein to nominally pulse once per heart beat, but it is understood that the pump is being triggered from variations in the blood pressure, and thus the pump may execute a pump/transfer stroke sequence at more or less than the cardiac cycle.

[00135] Above the threshold pressure needed to overcome the aortic pressure, the outflow rate will be determined by pressure differential across actuator plate **210**, and therefore also by coil current I. These factors lead to choice of an optimum ejection rate by determining I, t_{pump}, and

$t_{transfer}$ that requires the lowest stroke energy. It is advantageous, both energetically and to minimize blood shear rate, to perform most of each stroke near this optimum rate. Thus outflow will typically still be near its mean rate when the pump reaches the end of its ejection stroke.

[00136] During the wait between the end of a transfer stroke and the beginning of the next ejection stroke, there is no coil current ($I = 0$), and thus no electrical dissipation. It is preferred that during this waiting state that actuator plate **210** is resting without tabs **211** contacting actuator stops **233**. The blood in chamber **220a** is thus pressurized by the action of the net bias force with a pressure of F_{bias}/A. During diastole, the pressure F_{bias}/A is not large enough to open valve **205**, and thus actuator plate will remain with chamber **220a** at or near minimum volume. When the ventricle pressure rises, the pressure in chamber **220b** will rise accordingly until valve **205** opens. This will ensure that an increase in the pressure of the **LV** will result in movement in actuator plate **210** that can be sensed to trigger pump **200**. The rising ventricle pressure is augmented by the net bias force produced by the springs, so that the pressure in chamber **220a** exceeds the aortic pressure, allowing detectable motion of the actuator plate, long before ventricle pressure would be sufficient to overcome aortic pressure. Aortic root flow is possible only if **LV** systole persists into the transfer stroke.

[00137] Since the force and thus total pressure blood pressure generated within each chamber **220** is approximately independent of the position of the armature **210** and is dependent on the coil current, as indicated by Equation 9, the pressure is easily controllable and can be electrically adjusted. In particular, it may be desirable to periodically adjust the threshold or to periodically test the effect of modifying the threshold for improved pump performance or to alter the amount of energy exerted by the pump, and thus the amount of work required by the patient's heart **H**. The threshold in the device of the present invention can be adjusted electronically from pulse to pulse, if required. One method of adjusting the threshold is to apply a small current to the coils between pulses. Another method of adjusting the threshold is by changing the amount of actuator plate movement or chamber pressure required to trigger the pump. Electronic adjustment of the threshold permits programming the threshold at which the transfer stroke is initiated at the start of LV systole. Since the coil dissipation is proportional to I^2R (Equation 5), and the current needed for such threshold adjustment is small relative to the driving current, the energy and efficiency cost of electrically modifying the threshold setting is modest.

Ventricular Assist System—Control and Coordination with Heart during Arrhythmias

[00138] Patients with ventricular arrhythmias needing ventricular assist are normally provided with bi-ventricular support. However, there is anecdotal evidence that patients on LVADs can tolerate arrhythmias, and thus patents with ventricular arrhythmias may in the future receive LVAD support under some conditions. In particular, it is important that patents receive an adequate amount of circulatory support to reduce the potential for reduced perfusion and increased risk of thromboembolic complications (primarily due to stasis, pooling, dilation). The experience at the Cardiovascular Devices Division of the University of Ottawa Heart Institute, with animals supported on assist devices and subjected to ventricular fibrillation (VF), found that sustained periods of maximal support by the device can lead to recovery from extended periods of VF and return to sinus rhythm. In addition, long term circulatory support (weeks) in animals with refractory VF was able to maintain sufficient blood flow to eliminate the risk of perfusion deficit and thromboembolic events by utilizing active filling modes.

[00139] Currently most ventricular assist devices run in two principal modes, which can provide either passive (no suction) or active (utilizing suction) filling modes. In addition, these devices use principally use two operating rates: either a fixed rate (rate is set to a specific operating rate measured in beats per minute – BPM) or an automatic mode (rate derived from sensors determining end points i.e. position at fill, empty, etc). Both of these operating rates have drawbacks under certain physiological states. For instance, fixed rate works well in at a given level of activity. However, if the activity level of the recipient is increased the pump does not provide sufficient output to match the physiological requirements. Automatic mode, on the other hand, may not respond adequately in the case of atrial and/or ventricular arrhythmias (abnormal heart rhythms) and other physiological states such as hypovolaemia (decreased volume of circulating plasma).

[00140] One embodiment of the present invention includes a blood pump having a control system for use during arrhythmias. Specifically, the schematic of FIG. 17 provides the required control by using an automatic mode switching approach **1700**. The structure of the proposed device allows a more accurate determination of the actual physiological state (e.g., LV contraction), than non-pulsatile pumps. This allows the controller to sense abnormal

physiological states and switch to alternative operating modes. The intent is to allow the device to maximize blood pumped through the arterial system, if and when the natural heart cannot pump blood (either partially or totally). This is especially important during periods of low blood volume (hypovolemic conditions), during electrical disturbances such as arrhythmias (including atrial, ventricular, and/or supraventricular arrhythmias) or periods of low ventricular contractility. The most important factor during these low flow conditions is to reduce the potential for perfusion deficit or thromboembolic events.

[00141] As shown in FIG. 17, the previously described method of detecting LV contraction is used for normal heart contractions, i.e., by detection of pusher-plate (armature) motion during the wait period following the transfer stroke. When LV contraction is detected, the device immediately executes a normal pumping cycle, i.e., a pump stroke followed by a transfer stroke. During normal physiologic conditions, detection of LV contraction should occur within a given time period following completion of the previous eject/transfer cycle. Conversely, failure to detect LV contraction within this time window is consistent with one of the abnormal physiologic states (hypovolemia, arrhythmia or low contractility) associated with poor heart function. If LV contraction is not detected within the expected time window, then a pump/transfer cycle will be triggered upon expiration of the time window. This ejection is in effect fixed-rate, occurring a set time after completion of the previous pump/transfer cycle. This effectively ensures a minimum allowable pump rate. Combined with the active filling inherent in this pump configuration, this algorithm measures a minimum level of pump output, reducing the potential harmful effects of arrhythmias and other low-flow conditions.

Sensors for the Control of Ventricular Assist System

[00142] The pumping of blood through ventricular assist system **22** results, in part, from current waveforms supplied to coils **207** as controlled by controller **40**. The dynamics of pump **200** as described above can be controlled from signals indicating one or more of the following: the pressure in one or more of chambers **220**, the position, velocity or acceleration of actuator plate **210**, and the current through coils **207**. In a preferred embodiment, pump **200** is controlled using sensors for the current of coil **207** and the position of actuator plate **210**. Many techniques for measuring current are know in the field. The measurement of the position of the suspended

actuator plate is preferably done without contact with the plate. Discussion of several techniques for measuring the position of the actuator plate and the pressure within the pump follows.

Actuator plate position measurements

[00143] Several techniques for measuring the position of the actuator plate have been tested, including but not limited to load cells to measure the stress on springs **231**, eddy current proximeters in or on frame **209** to detect the presence of magnets **601,** a linear differential transformer (LVDT), analog-output Hall-effect sensors, and directly detecting field change caused by armature motion. Since there are no bearings or guides on armature **210**, the armature can tilt during operation due to dynamic pressure gradients across chambers **220**. Thus, at last two spring sensors, LVDT or eddy current sensors are required on opposite sides of armature **210** to obtain a correct position signal.

[00144] One position sensor of armature 210 measures the voltage across coils 207, and in particular changes in the voltage resulting from field changes due to armature motion on the drive circuit. Specifically, the drive coil voltage is given by:

$$V = IR + L \cdot dI/dt + kQ \tag{10}$$

where I = coil current I, R = coil resistance, L = coil self-inductance L, and Q is the signed pump flow. Typically, kQ term is about 10 mV/(ml/sec), R is about 6 Ω and L = 33 mH. The IR and L·dI/dt terms are compensated by analog circuitry in the electronics. Variation of coil resistance R with temperature and hence with pumping power can be accounted for by including a thermistor to measure coil temperature. The remaining output voltage, representing the kQ term, is integrated. The linearity of this technique is adequate for controlling pump **200**.

[00145] An alternative position detector embodiment is to measure the induced voltage in a coil added to frame **209**. This is illustrated in FIG. 13 as a pair of small sensor coils **1301a** and **1301b** provided in an annular groove of a face of pole **801a'** of pump **200'.** Coils **1301** intercept only part of the magnetic flux determined solely by the geometry of pump **200'**. The flow of current through coils **1301** is negligible, and so they can be wound with smaller wire with little dissipation. A fraction of the self-induced voltage (L·dI/dt term) is still present, but this is also determined purely by coil and pole geometry.

[00146] Since sensor coils **1301** respond to armature velocity they are ideal for their most critical function -- detecting the start of motion of actuator plate **210'** to initiate the pump stroke. To produce the pump volume waveform needed for cycle control, system monitoring, and calculating pump output, the velocity waveform must also be integrated. The endpoints must therefore also be determined to calibrate integrator zero and verify span. In principle this can be done directly by observing the abrupt change in velocity drop if and when the armature **210'** hits armature stops **233'** at the end of the pump stroke. For a multiyear design, it is preferred to minimize such impact which could cause wear, and wastes energy.

[00147] Several techniques are available to perform short-range end-of-stroke detection, also known as full-fill (FF) and full-eject (FE) sensing, and not shown in the figures. One alternative is to place short-range Hall sensors on the frame (also referred to herein as the stator) to sense the outer edges of the magnets **601**. The sensors are placed in small notches in the stator, where they are shielded from the field until the corner of the magnet overlaps the notch. Again, the function is controlled by structural geometry, eliminating need for recalibration.

[00148] Though drive coil voltage cannot determine pump volume and flow as accurately as some other sensors, the voltage is easy to measure and is thus available as a backup or "failsafe" control signal in the event of sensor, electronics, or cable failure. Since the drive coil circuit must be intact to operate the VAD at all, it can be controlled whenever it can be operated. Specifically, the device can be operated with only two wires leading to pump **200.**

[00149] In principle, all control functions can be accomplished using this signal alone, though control precision may degrade. As noted above, a steady coil current may be commanded during a "wait" interval to modify the eject assist pressure. During this interval, when the pump is not moving and the current is constant, the coil voltage is simply IR. Thus the slowly varying value of resistance can be measured and compensated for. Alternatively, a test current may be introduced solely for this purpose. The stroke endpoints may be determined by detecting the abrupt rate change as the pusher plate hits its end stops.

Pump Pressure Sensing

[00150] Under normal operating conditions, measurements of the position of actuator plate **210** and coil current I provide sufficient information to control pump actuation appropriately,

responding to changes in preload (filling conditions, e.g. LV pressure) or afterload (aortic pressure). Since the force exerted on actuator plate **210** is a function of the coil current and net bias force, knowledge of the coil current I during the pump stroke provides an indication of the difference in pressure (ΔP) between the pre-chamber (the LV Pressure in chamber **220a**) and pumping chamber (the aortic pressure in chamber **220b**). Under certain circumstances, it might be beneficial to know the actual filling or ejecting pressures, not merely the difference between them. For instance, an abnormally high ΔP for a given eject rate could be the result of either an inflow conduit occlusion (causing an abnormally low filling pressure) or an outflow conduit occlusion (causing an abnormally high ejecting pressure). A measurement of either pressure, together with the ΔP value derived from the coil current during ejection, would provide values for the actual filling and ejecting pressures. This would allow a simple differentiation between, for instance, an inflow occlusion and an outflow occlusion. It would also facilitate response to extremely poor preload conditions. In particular, knowledge of a negative pressure within the pre-chamber or filling tract would provide a direct indication of inflow occlusion or inadequate preload.

[00151] One possible means of pressure detection is shown in Figure 14 for a pump **200"**. A region **1401** of pump sac **221a"**is left unbonded to frame **209"**. The unbonded region **1401** may be over the pole **801a"**, as illustrated, or in any non-flexing portion of the pre-chamber, e.g., in its inflow or outflow port, or somewhere in the inflow conduit. A means is provided to detect deflection of the unbonded sac region, such as would occur if the pressure within the pre-chamber were to become negative. The motion is preferably detected by an optical sensor **1403** (e.g., an LED and photo-detector) or any other appropriate means of detecting inward deflection of the sac. Thus, a negative pressure within the pre-chamber would be identified through detection of sac motion.

Alternative Pump Embodiments

[00152] The electromagnetic drive, spring suspension, control, and other aspects of the present invention can be incorporated into pump designs using two variable-volume chambers connected in series. In particular, series-displacement pumps have been described in the '60 patent. Thus for example, FIG. 15 shows pump **1500**. Pump **1500** is a pump having the variable-volume

chamber design of the series displacement pump of the '601 patent and the electromagnetic structure **800** of the present invention. Specifically, the transfer portion between the variable-volume chambers is provided by an external transfer portion **1501** that includes a one-way valve to control flow through the chambers. Another alternative embodiment is shown as pump **1600** in FIG. 16. Pump **1600** includes a transfer port **1601** on the side of pump **1600** opposite the blood inflow. Generally, the transfer port can be positioned at nearly any orientation relative the inflow and outflow, such as 90 degrees or any other convenient angle.

[00153] BVAD operation can be achieved using one of the two following embodiments. If the first BVAD embodiment, a patient **P** is provided with two separate pumps, a LVAD and a RVAD. These pumps are separately provided with net bias forces as described above for the right and left ventricles.

[00154] A second BVAD embodiment incorporates the electromagnetic structure **800** and the spring suspension of the present invention with the chamber valving of the BVAD pump configuration of the '601 patent. In the BVAD of the '601 patent, each of a pair of chambers has a pair of one-way valves. In the present invention, each chamber is adapted to pump one of the two ventricles. Since the pumping requirements of the two ventricles differ, with the left side having a higher pressure than the right, the bias force of the energy storage mechanism can be adjusted to load level the drive utilization. Specifically, the bias force is applied towards the chamber pumping from the left ventricle. This provides a much improved operation of the BVAD of that patent by providing a net bias force that favors the left ventricle. Specifically, when pumping the right ventricle, a portion of the electromagnetic drive energy is stored in the springs, and the pump delivers blood at a low pressure. When pumping the left ventricle, the electromagnetic drive energy is augmented by recovered spring energy to provide the higher pressure required by the left ventricle. The net bias force can thus be selected to load level the energy of the electromagnetic drive between the right and left pumping strokes.

[00155] The invention has now been explained with regard to specific embodiments. Variations on these embodiments and other embodiments may be apparent to those of skill in the art. It is therefore intended that the invention not be limited by the discussion of specific embodiments. It is understood that the examples and embodiments described herein are for

illustrative purposes only and that various modifications or changes in light thereof will be suggested to persons skilled in the art and are to be included within the spirit and purview of this application and scope of the appended claims.